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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,652	04/02/2004	Tadashi Hayashi	00862.018048	8200

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EXAMINER	
BOWERS, NATHAN ANDREW	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/815,652	HAYASHI, TADASHI	
	Examiner	Art Unit	
	NATHAN A. BOWERS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,7,9 and 11-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 6, 7, 9 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Buican (US 5100627).

Buican discloses a target object modification apparatus comprising an aligner device configured to manipulate a posture of a supplied target modification minute object. Buican discloses a microfluidic chip that includes a manipulation area (Figure 2:68) within which supplied biological cells are handled using optical trapping procedures. This is disclosed in column 3, line 44 to column 4, line 8. A first feed means configured to supply the target modification minute object (biological cell), and a second feed means configured to extract the target modification minute object from the manipulation area are provided. Additionally, a plurality of first and second injection means (Figure 2:58-62) are used to deliver first and second modifiers onto the surface of the target modification minute object while in the manipulation area. This is disclosed in column 4, lines 9-25. It is clear from Figure 2 that the aligner device at the manipulation area is positioned between injection means located on opposite sides of the microfluidic chip.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2) Claims 1, 6, 9, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gruber (US 20030119177) in view of Griner (US 5266272).

With respect to claims 1 and 13, Gruber discloses a target object modification apparatus and method that includes the use of an aligner device for producing an optical trap capable of manipulating the posture of a supplied target modification minute object within a reaction chamber. This is disclosed in paragraphs [0015]-[0022]. Paragraph [0059] indicates that a feed means (Figure 4:42) is provided for supplying cells (Figure 4:59) and that injection channels (Figure 4:44) are provided for supplying modifiers. The optical trapping aligner device restricts the movement of the cells within a chamber formed by the intersection between the feed means and the injection channels. In Figure 2C, Gruber discloses an embodiment in which a feed

means and first and second injection channels intersect to form a reaction chamber. Modified cells are extracted using second feed means (Figure 4:48). Gruber additionally teaches in paragraph [0063] that syringes are used as first and second injection means to deliver modifiers to the first and second injection channels. Gruber, however, does not clearly state that a carriage is used to align the first and second injection means with the first and second injection channels.

Griner discloses a fluidic device for adding modifiers and other reagents to a biochip. In column 12, lines 15-38, Griner indicates that a plurality of reagent vials (Figure 20:42) are provided with corresponding tubing (Figure 20:154) in communication with various injection ports (Figure 18:158). The injection ports are supported on a carriage (Figure 20:148) that is aligned with each inlet on the biochip.

Gruber and Griner are analogous art because they are from the same field of endeavor regarding microfluidic cell modification apparatuses.

At the time of the invention, it would have been obvious to alter the apparatus and method of Gruber in order to provide each of the injection means on a carriage capable of aligning with each feed means and injection channel. The use of movable injection means provided on a carriage would be beneficial because it would allow one to add reagents to a plurality of aligner devices using the same injection means. Griner teaches that the attachment of an injection device to a cartridge is desirable because the movement of the cartridge from one aligner device to another can be regulated effectively using an automated control system.

With respect to claim 6, Gruber and Griner disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejections above. In addition, Gruber teaches in paragraph [0074]

that fixing devices (Figure 5:72) are used to stably fix and restrain modified target modification minute objects in the reaction area.

With respect to claim 9, Gruber and Griner disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejections above. Gruber additionally indicates in Figure 2 that a plurality of aligner devices are arranged in an array in order to simultaneously modify a plurality of target modification minute objects.

With respect to claim 11, Gruber and Griner disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejections above. Gruber further states that the first and second feed means are capillaries with electrodes. Paragraph [0067] indicates that electrodes are provided within each of the fluid channels in order to create electro-osmotic flow.

3) Claims 1, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buican (US 5100627) in view of Griner (US 5266272).

With respect to claims 1 and 13, Buican discloses the target object modification apparatus as previously described above. Buican discloses a microfluidic chip that includes a manipulation area (Figure 2:68) within which supplied biological cells are handled using optical trapping procedures. This is disclosed in column 3, line 44 to column 4, line 8. A first feed means configured to supply the target modification minute object (biological cell), and a second feed means configured to extract the target modification minute object from the manipulation area are provided. Additionally, a plurality of first and second injection means (Figure 2:58-62) are used

to deliver first and second modifiers onto the surface of the target modification minute object while in the manipulation area. Buican, however, does not clearly state that a carriage is used to align the first and second injection means with the first and second injection channels.

Griner discloses a fluidic device for adding modifiers and other reagents to a biochip. In column 12, lines 15-38, Griner indicates that a plurality of reagent vials (Figure 20:42) are provided with corresponding tubing (Figure 20:154) in communication with various injection ports (Figure 18:158). The injection ports are supported on a carriage (Figure 20:148) that is aligned with each inlet on the biochip.

Buican and Griner are analogous art because they are from the same field of endeavor regarding microfluidic cell modification apparatuses.

At the time of the invention, it would have been obvious to alter the apparatus and method of Buican in order to provide each of the injection means on a carriage capable of aligning with each feed means and injection channel. The use of movable injection means provided on a carriage would be beneficial because it would allow one to add reagents to a plurality of aligner devices using the same injection means. Griner teaches that the attachment of an injection device to a cartridge is desirable because the movement of the cartridge from one aligner device to another can be regulated effectively using an automated control system.

4) Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Gruber (US 20030119177) or Buican (US 5100627) each in view of Griner (US 5266272) as applied to claim 1, and further in view of Hoffman (US 4989623).

The combination of Gruber and Griner and the combination of Buican and Griner each disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that a recovery mechanism is provided for cleaning and sterilizing the injection means.

Hoffman discloses an apparatus for cleaning the pipette tip of an injection means capable of introducing biological compounds into an analytical system. Hoffman teaches that the pipette tip (Figure 1:4) is automatically moved by a controller to a wash station (Figure 1:10) where the pipette tip is sterilized. This is disclosed in column 2, lines 19-39 and column 3, lines 1-15.

Gruber, Buican, Griner and Hoffman are analogous art because they are from the same field of endeavor regarding biological analysis systems.

At the time of the invention, it would have been obvious to clean and sterilize the sample injection means disclosed by the combination of Gruber and Griner and the combination of Buican and Griner. Hoffman teaches that disinfecting solutions such as bleach are well known in the art and capable of effectively cleaning an injection device in between uses. Hoffman additionally teaches that robotic pipette actuation systems are additionally advantageous because they allow one to automatically move an injection means from the analytical apparatus to a wash station.

Response to Arguments

Applicant's arguments filed 13 February 2008 with respect to the 35 U.S.C. 103 rejections involving the combination of Braff with Chou have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further

consideration, a new ground of rejection is made in view of the Buican reference, as well as the combination of Buican with Griner and the combination of Gruber with Griner.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/Nathan A Bowers/
Examiner, Art Unit 1797